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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/509,279 | 05/05/2005 | Silvia Fonquerna Pou | 09605.0001 | 1079 |
| 22852 | 7590 | 07/03/2008 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | EXAMINER GALLIS, DAVID E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 07/03/2008 PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,279

Applicant(s)

POU ET AL.

Examiner

DAVID E. GALLIS

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 28 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) 4, 23-26 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 12, 15-19, 21 and 28 is/are rejected.
- 7) ☒ Claim(s) 8-11, 13, 14, 20 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/28/04 and 6/16/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 through 26, 28, and 31 through 33 are pending. Claims 1, 5, 7, 10 through 16, 18, 20, 22 through 26, 28, 31, and 32 have been amended. Claims 27, 29, and 30 have been cancelled. Claims 4, 23 through 26, and 31 through 33 have been withdrawn from consideration. Applicants' claim to priority from foreign application SPAIN P200200753 filed April 1, 2002 is acknowledged.

Election/Restrictions

2. Applicant's election of Group I, claims 1 2, 3, 5 through 22 and 28 through 16 is acknowledged. Applicant has elected Group I without traverse, therefore, the election is hereby MADE FINAL. The subject matter for the elected Group I is as follows:

- I. Group I, claims 1, 2, 3, 5 through 22, and 28, drawn to a compound and composition of formula I, wherein only one of A, B, C, and D is a nitrogen atom, classified in class 546, and various subclasses.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1 through 3, 5 through 7, 12, 15 through 19, 21 and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Cai et al. (WO 02/14317, February 21, 2002 and WO 02/020013, March 14, 2002, both cited by Applicants).

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5. Claims 1 and 28 are drawn to a compound of formula I and a pharmaceutical composition comprising a compound of formula I. Claims 2, 3, 5 through 7, 12, 15 through 19, and 21 further limit claim 1 and intervening claims to specific formula I functional groups and bonds.

6. Cai et al. clearly anticipate these claims teaching compounds of instant formula I wherein L_1 and L_2 are single bonds, n is equal to 0, X is oxygen, R_7 is alkyl (t-butyl), R_4 and R_5 are hydrogen, A , B , C , and D are singularly the only ring nitrogens, R_6 can be hydrogen or dialkylamino (dimethylamino or N-morpholinyl), and R_2 is hydrogen or oxide. See the compounds of WO 02/14317 page 58, paragraph B; page 60, paragraph B; page 62, paragraph C; page 65, paragraph D; page 68, paragraph D; page 71, paragraph C.

7. These structures also anticipate the functional group and bond limitations of claims 2, 3, 5 through 7, 12, 15 through 19, and 21.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 through 3, 5 through 7, 12, 15 through 19, 21 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Filla et al. (WO 98/20875, May 22, 1998).

10. Claims 1 and 28 are drawn to a compound of formula I and a pharmaceutical composition comprising a compound of formula I. Claims 2, 3, 5 through 7, 12, 15

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through 19, and 21 further limit claim 1 and intervening claims to specific formula I functional groups and bonds.

11. Filla et al. clearly anticipate these claims teaching compounds of instant formula I wherein L_1 and L_2 are single bonds, n is equal to 0, X is oxygen, R_7 is alkyl (t-butyl), R_4 and R_5 are hydrogen, A is the only ring nitrogens, and R_6 is amino (see page 28, Preparation IV).

12. This structure also anticipates the functional group and bond limitations of claims 2, 3, 5 through 7, 12, 15 through 19, and 21.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 1 recites R_2 to represent $L_3-(W_2)_p$, wherein L_3 can be a single bond and p can be equal to 0. Such a group represents an unassociated single bond (a single bond with nothing attached). Correction or clarification is required.

Claim Objections

16. Claims 8, 9, 10, 11, 13, 14, 20, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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17. Claim 22 is objected to because of the following informalities: Page 22, 5th compounds is recited as "ter-butyl" instead of tert-butyl; Page 22, 8th compound is actually two compounds requiring a line break. Appropriate correction is required.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David E. Gallis
Patent Examiner

/ Bernard Dentz/

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Primary Examiner, Art Unit 1625